DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 20, 2015

ALLIANCE INTERNATIONAL CO., LTD.
JEN KE-MIN
OFFICIAL CORRESPONDENT
NO.54 YING TAO RD. YING DISTRICT
NEW TAIPEI CITY, 239 23942, TAIWAN

Re: K132663
Trade/Device Name: i-QARE DS-W Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: March 31, 2015
Received: April 10, 2015

Dear Jen Ke-min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k132663

Device Name
i-QARE DS-W Blood Glucose Monitoring System

Indications for Use *(Describe)*
The i-QARE DS-W Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The i-QARE DS-W Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The i-QARE DS-W Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The i-QARE DS-W Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).
The i-QARE DS-W Draw-in Blood Glucose Test Strips are for use with the i-QARE DS-W Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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E-mail: miller.brenda@gmail.com

5. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

5.1. General Information Establishment

- The assigned 510(k) number is : **K 132663**
- Manufacturer: Alliance International Co., Ltd.
- Address: No.54, Ying Tao Rd. Yinge District, New Taipei City, 239, Taiwan, R.O.C.
- Owner Number: **9099902**
- Contact Person: Dr. Jen, Ke-Min
  E-mail: ceirs.jen@msa.hinet.net
  (Tel)+886-2-86781007;
  (Fax)+886-2-86781006
- Date Prepared: March 27, 2015
- Proprietary Name**:** i-QARE DS-W Blood Glucose Monitoring System
  Trademark: i-QARE
  Model: DS-W (i.e. "DS-Walkie")
- Common Name**:** Blood Glucose Monitoring System
- Classification Name**:** SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER, Class II
- **Product Code:** NBW

5.2. Safety and Effectiveness Information

- **Predicate Device:**
  Claim of Substantial Equivalence (SE) is made to DS-A Blood Glucose Monitoring System **(K082965)**

- **Device Description:** Based on an electrochemical biosensor technology and the principle of capillary action, i-QARE DS-W Blood Glucose Monitoring System only needs a small amount of blood. Capillary action

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- at the end of the test strip draws the blood into the action chamber and your blood glucose result is precisely and displayed in 6 seconds.

- **Intended Use:**

  The i-QARE DS-W Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The i-QARE DS-W Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The i-QARE DS-W Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The i-QARE DS-W Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). The i-QARE DS-W Draw-in Blood Glucose Test Strip are for us with the i-QARE DS-W Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

- **Synopsis of Test Methods and Results**

  Pre-clinical and clinical data are employed upon submission of this 510(K) premarket notification according to the *Guidance Document for In Vitro Diagnostic Test System; Guidance for Industry and FDA* document provided by CDRH/ FDA.

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Comparison Table

Similarities:

Item	Predicate device	Subject device
Manufacturer	Alliance International	Alliance International
Proprietary Name:	DS-A Blood Glucose Monitoring System	i-QARE DS-W Blood Glucose Monitoring System
510(k) No.	**K082964**	**K132663**
Indications for use	The A-CHECK DS-A Blood Glucose Monitoring System is used with DS-A Test Strips and 3-level Controls for the measurement of glucose in fresh capillary whole blood from the finger. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by person with diabetes, or in clinical setting by health care professionals, as an aid to monitor the effectiveness of diabetes control. There are not intended for diagnosis of or screening for diabetes mellitus, and are not intended for use on neonates.	The i-QARE DS-W Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The i-QARE DS-W Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The i-QARE DS-W Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The i-QARE DS-W Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). The i-QARE DS-W Draw-in Blood Glucose Test Strip are for us with the i-QARE DS-W Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.
Test Principle	Electrochemical biosensor with carbon electrodes	same
Measuring Time	6 sec	same
Detecting Range	20 ~ 600 mg/dL	same
Operating Temperature	10 to 40 ℃	same

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Strip Storage Temperature	4 to 32 ℃	same
Battery Power	One 3V Lithium CR 2032 battery	same
Data Recall	By button (memory capacity: 20 sets)	same

Differences:

Item	Predicate device	Subject device
Limitations	DS-A Draw-In test strips are designed for use with fresh capillary whole blood sample. Do Not use serum or plasma samples. 1. It should not be used in Intensive Care settings or if the patient is dehydrated, hypotensive, hypoxic, in diabetic ketoacidosis, in shock, or in a hyperglycemic/hyperosmolar state. 2. Hematocrit: Variation in sample hematocrit between 30% and 55% has no significant effect on test results. Very high (above 55%) and very low (below 30%) hematocrit can cause inaccurate results. 3. Neonates: Do not use Draw-In test strips to test neonates. The performance of this system has not been validated with neonatal samples. 4. Blood concentration of Ascorbic Acid > 1.2mg/dL or Uric Acid > 7mg/dL will cause overestimation of blood glucose results. 5. Therapeutic levels of L-dopa (>10mg/dL) or Dopamine (> 1.25mg/dL) may result in inaccurate (elevated) glucose readings with the system. 6. Acetaminophen (<20mg/dL),	1. Apply only capillary whole blood sample to test your blood glucose level. 2. For over-the-counter use 3. Not for screening or diagnosis of diabetes mellitus 4. Alternative site testing (AST) testing should only be done during steady-state times (when glucose us not changing rapidly) 5. AST should not be used to calibrate continuous glucose monitors (CGMs) 6. AST should not be used for insulin dose calculations 7. Not for neonatal use which will cause inaccurate result. 8. For single-patient use only 9. The Blood Glucose Monitoring System is not for use in the critically ill. 10. This system should not be used on persons who are in shock, are dehydrated, or who are hyper-osmolar. 11. The following substances may cause interference at levels above the following concentrations: • Dopamine - 0.02 mg/dL • L-Dopa – 0.712 mg/dL • Methyldopa - 0.9 mg/dL • Uric Acid - 6 mg/dL • Triglycerides - 1900 mg/dL

	Ibuprofen (<40mg/dL), Tetracycline (< 0.4mg/dL), Tolbutamide (<100mg/dL), Cholesterol (<500mg/dL), and Creatinine (<30mg/dL) may not affect the glucose meter readings.	• Ascorbic Acid - 4.7 mg/dL • Acetaminophen – 20 mg/dL • Cholesterol – 500 mg/dL 12. The acceptable hematocrit range is 20-60%. If your hematocrit is outside of this range, your blood glucose result may not be accurate. 13. Please read your test strip instructions carefully for additional health-related
Meter Weight	56 g	46g (exclude battery)
Meter Dimension	94.5mm x 56mm x 27.5mm	47.5mm x76.5 mm x 21.9mm
Button Design	Two buttons	One button
Sample Volume	1μL	0.7μL
Specimen Type	capillary whole blood from the fingertip	capillary whole blood from the fingertip, palm, and forearm
Control solution	Level 1, Level 2, Level 3	Level 1, Level 2
HCT Range	30 ~ 55 %	20 ~ 60 %
Memory Storage	360 test results	20 test results
Meter Coding	Code Card	Code card free
Meter Check	Resistor (Code Card)	Built-in code (Code card free)

- Substantial Equivalence (SE) Discussion

Both of them have the same working principle and technologies including fresh capillary whole blood, measuring time, detecting range, operating temperature, strip storage temperature, battery power, data recall.

The difference comparisons between the subject device DS-W and the predicate device DS-A Blood Glucose Monitoring System (K082965) are as follows,

1) The subject device uses the capillary whole blood from alternate site including the palm and forearm, and the predicate device uses the capillary whole blood from fingertip only. Since the testing results of alternate site for the subject device have been validated, more sites for drawing blood bring more convenience.
2) The subject device control solutions, Level 1/Level 2 are the same as those of Level 1/Level 2 for the predicate device, which are already 510(k)-clearance. There are no safety and effectiveness concerns.
3) The subject device has 13 limitations and predicate device has 6 ones. Though more limitations mean more restrictions on usage, it leads to more accurate and reliable testing results, thus more safety is ensured.

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4) The DS-W is smaller and lighter than DS-A; and DS-W is designed to be the simplest model by the same applicant, Alliance International Co., Ltd., and DS-W is created using only one button for operation. Smaller volume and lighter weight bring more convenience on usage, i.e., fewer hazards.
5) Due to the needs of customers and market, the smaller volume of blood sample is more acceptable than 1μL, thus, DS-W develops a smaller volume of 0.7μL and alternate site testing from the palm and forearm without affecting the test results.
6) The subject device enlarges the HCT range for more users to test their blood sugar in accurate results. In the HCT report, the accurate test results for the larger range have been validated. The results were all within ±15% acceptable range.
7) The design concept of DS-W is to be simple, 20 sets of memory for users to recall the latest test results without getting confused in selecting too many data of 360 sets for predicate device.
8) In order to avoid customers forgetting to code the meter and getting wrong test results, the subject device DS-W has developed Code card free function to avoid this hazard.

The subject device completed relevant clinical and performance tests. The differences between the subject device and the predicate device are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical uses of the device. Therefore, these differences do not raise any safety and effectiveness concerns. They are substantially equivalent.

- Conclusions:

The conclusions drawn from the clinical and the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate devices.